General

Guideline Title

Alternatives to hysterectomy in the management of leiomyomas.

Bibliographic Source(s)

American College of Obstetricians and Gynecologists (ACOG). Alternatives to hysterectomy in the management of leiomyomas. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2008 Aug. 14 p. (ACOG practice bulletin; no. 96). [117 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American College of Obstetricians and Gynecologists (ACOG). Surgical alternatives to hysterectomy in the management of leiomyomas. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2000 May. 10 p. (ACOG practice bulletin; no. 16). [64 references]

The American College of Obstetricians and Gynecologists (ACOG) reaffirmed the currency of this guideline in 2012.

Recommendations

Major Recommendations

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of "Major Recommendations" field.

The following recommendations and conclusions are based on good and consistent scientific evidence (Level A):

Abdominal myomectomy is a safe and effective alternative to hysterectomy for treatment of women with symptomatic leiomyomas.
Based on long- and short-term outcomes, uterine artery embolization is a safe and effective option for appropriately selected women who wish to retain their uteri.
Use of gonadotropin-releasing hormone (GnRH) agonists have been shown to improve hematologic parameters, shorten hospital stay, and decrease blood loss, operating time, and postoperative pain when given for 2–3 months preoperatively. Benefits of preoperative use of GnRH agonists should be weighed against their cost and side effects for individual patients.
Several studies suggest that the infiltration of vasopressin into the myometrium decreases blood loss at the time of myomectomy.

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

The clinical diagnosis of rapidly growing leiomyomas should not be used as an indication for myomectomy or hysterectomy.
Hysteroscopic myomectomy is an accepted method for the management of abnormal uterine bleeding caused by submucosal leiomyomas.

The following recommendations and conclusions are based primarily on consensus and expert opinion (Level C):

There is insufficient evidence to support hysterectomy for asymptomatic leiomyomas solely to improve detection of adnexal masses, to prevent impairment of renal function, or to rule out malignancy.
Leiomyomas should not be considered the cause of infertility, or significant component of infertility, without completing a basic fertility evaluation to assess the woman and her partner.
Hormone therapy may cause some modest increase in uterine leiomyoma size but does not appear to have an impact on clinical symptoms. Therefore, this treatment option should not be withheld from women who desire or need such therapy.
The effect of uterine artery embolization on pregnancy remains understudied.

Definitions:

Grades of Evidence

I Evidence obtained from at least one properly designed randomized controlled trial.

II-1 Evidence obtained from well-designed controlled trials without randomization.

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Levels of Recommendations

Level A - Recommendations are based on good and consistent scientific evidence.

Level B - Recommendations are based on limited or inconsistent scientific evidence.

Level C - Recommendations are based primarily on consensus and expert opinion.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Uterine leiomyomas (fibroids)

Guideline Category

Evaluation

Management

Treatment

Clinical Specialty

Obstetrics and Gynecology

Surgery

Intended Users

Physicians

Guideline Objective(s)

To aid practitioners in making decisions about appropriate obstetric and gynecologic care
To review the literature about medical and surgical alternatives to hysterectomy and to offer treatment recommendations

Target Population

Women with uterine leiomyomas

Interventions and Practices Considered

Treatment/Management

Surgical Alternatives to Hysterectomy

- Abdominal myomectomy
- Laparoscopic myomectomy
- Hysteroscopic myomectomy
- Uterine artery embolization
- Magnetic resonance imaging-guided focused ultrasound surgery (considered, but not specifically recommended)

Adjunctive Medical Treatment

- Preoperative adjuvant therapy: gonadotropin-releasing hormone agonists (GnRH)
- Intraoperative adjuvant therapy: vasopressin infiltration into the myometrium
- Medications considered but not specifically recommended:
  - Contraceptive steroids and nonsteroidal anti-inflammatory drugs
  - Aromatase inhibitors
  - Progesterone modulators

Major Outcomes Considered

- Morbidity and mortality
- Recurrence of leiomyomas
- Risk of follow-up treatment, including unplanned hysterectomy

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

2008 Original Guideline

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' (ACOG's) own internal resources were used to conduct a literature search to locate relevant articles published between January 1985 and December 2007. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document.

Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

2012 Reaffirmation

The NCBI database was searched from 2008 to 2012. Committee members conducted a literature search with the assistance from the ACOG Resource Center staff who routinely perform the Practice Bulletin literature searches.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force.

I Evidence obtained from at least one properly designed randomized controlled trial.

II-1 Evidence obtained from well-designed controlled trials without randomization.

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

Methods Used to Analyze the Evidence

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

2008 Original Guideline

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

2012 Reaffirmation

The Committee on Practice Bulletins - Gynecology met in September 2012 and reaffirmed this document. A committee member reviewed the document and new literature on the topic. The document was then reviewed by the committee and the committee agreed that it is current and accurate.

Rating Scheme for the Strength of the Recommendations

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A - Recommendations are based on good and consistent scientific evidence.

Level B - Recommendations are based on limited or inconsistent scientific evidence.

Level C - Recommendations are based primarily on consensus and expert opinion.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate management of uterine leiomyomas

Potential Harms

Side Effects of Treatment

Abdominal myomectomy: In the long term, the risk of formation of new leiomyomas limits the efficacy of myomectomy. Another risk of myomectomy is the possibility of undergoing an unexpected hysterectomy because of intraoperative complications. This risk appears to be low (less than 1%) even when uterine size is substantial. Blood loss and the risk of transfusion may be increased in women with larger uteri.
Hysteroscopic myomectomy: As with abdominal leiomyomectomy, the effectiveness of the procedure decreases over time. One study of 274 procedures, with follow-up of more than 5 years, reported a success rate of 94.6% at 1 year, which decreased to 76.3% at 5 years. The reported complication rate for hysteroscopic myomectomy ranges between 1% and 12%, with rates of 1–5% reported in most studies. Potential surgical complications include fluid overload with secondary hyponatremia, pulmonary edema, cerebral edema, intraoperative and postoperative bleeding, uterine perforation, gas embolism, and infection.
Uterine artery embolization: In one reported randomized trial, minor complications, such as vaginal discharge, leiomyoma expulsion, and hematoma were higher in the group that had uterine artery embolization compared with those that had hysterectomy (58% versus 40%) as well as higher readmission rates for those undergoing uterine artery embolization (11.1% versus 0%). The rates of major complications were similar (4.9% for uterine artery embolization and 2.7% for hysterectomy).
Gonadotropin-releasing hormone (GnRH) agonists are expensive and no study has shown a significant decrease in transfusion risk or improvement in the quality of life. One surgical disadvantage to preoperative GnRH agonist therapy is that it may make the leiomyomas softer and the surgical planes less distinct.

It must be recognized that all surgical alternatives to hysterectomy allow the possibility for new leiomyomas to form, and preexisting leiomyomas that were too small to be detected or were intentionally not removed may exhibit significant growth, necessitating another procedure. Complications of other surgical procedures may lead to an unanticipated hysterectomy.

Qualifying Statements

Qualifying Statements

Qualifying Statements

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Patient Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2000 May (revised 2008 Aug; reaffirmed 2012)

Guideline Developer(s)

American College of Obstetricians and Gynecologists - Medical Specialty Society

Source(s) of Funding

American College of Obstetricians and Gynecologists (ACOG)

Guideline Committee

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Gynecology

Composition of Group That Authored the Guideline

Not stated

Financial Disclosures/Conflicts of Interest

Not stated

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Guideline Availability

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 933104, Atlanta, GA 31193-3104; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site .

Availability of Companion Documents

None available

Patient Resources

The following is available:

- Uterine fibroids. American College of Obstetricians and Gynecologists (ACOG); 2008.

Electronic copies: Available from the American College of Obstetricians and Gynecologists (ACOG) Web site .

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 933104, Atlanta, GA 31193-3104; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site .

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NGC Status

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